EU Declaration of Conformity

Legal Manufacturer:

Guilin HBM Health Protections, Inc.
No.1-2, Shuijing East Road, Economic and Technological Development Area, 541805 Guilin, Guangxi, China
SRN: CN-MF-000033439

EU Authorized Representative:

Continental Medical B.V.
Strevelsweg 700 303 Unit E7288 3083AS Rotterdam, Netherlands
SRN: NL-AR-000022261

Hereby declare in our own responsibility that the product:
Latex Surgical Gloves, sterile

Intended purpose: The surgical gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.

Product REF	Product Description
MLES55, MLES60, MLES65, MLES70, MLES75, MLES80, MLES85, MLES90 MSG7355, MSG7360, MSG7365, MSG7370, MSG7375, MSG7380, MSG7385, MSG7390	Disposable latex gloves

（1）
are in conformity with Regulation (EU) 2017/745 on medical devices

meeting the provisions of EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009 and ASTM D3577-19

Class IIa, Rule 7
Conformity assessment: Regulation (EU) 2017/745, Annex IX; Chapters I and III

Basic UDI-DI: 697178707SGNRUF
UMDNS Code: 11883
CND code: T01010202 SURGICAL GLOVES, LATEX
EMDN Code and Description: T01010102 - NON-POWDERED LATEX SURGICAL GLOVES

Notified body:
BSI Group The Netherlands B.V. Say Building,
John M. Keynesplein 9,
1066 EP, Amsterdam, Netherlands
Notified Body Number: 2797
Certificate No: MDR 747912 R000

（2）

are in conformity with Personal Protective Equipment Regulation (EU) 2016/425, under Category III risk set out in Annex I

meeting the provisions of EN ISO 21420:2020, EN ISO 374-1:2016 + A1:2018, EN ISO 374-5:2016

The products are subject to the procedure set out in:

- Annex V (EU type examination) of Regulation (EU) 2016/425 issued by

Notified Body:
ANCCP Certification Agency s.r.l.
Headquarters: Via dello Struggino 6, 57 121 LIVORNO (Italy)
Notified Body Number: 0302
EU type-examination certificate No: PPE-3338-23976-Cert

- Annex VIII (Module D) of Regulation (EU) 2016/425 under the supervision of

Notified body:
SATRA Technology Europe Limited
Bracetown Business Park Clonee, D15 YN2P, Ireland
CE No: 2777

GUILIN HBM HEALTH PROTECTIONS, INC.

Shun Huang

Huang Shun / Quality Director & PRRC

Place/date: Guilin, China, 2026-01-19